UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456 Master Case No. 01-12257-PBS
THIS DOCUMENT RELATES TO:	)	Subcategory Case No. 06-11337-PBS
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc., et al. v. Dey, Inc., et al., Civil Action No. 05-11084-PBS	)	

MEMORANDUM IN SUPPORT OF UNITED STATES' MOTION TO EXCLUDE CERTAIN OPINIONS OF W. DAVID BRADFORD, PH.D

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INTRODUCTION

The report of Dr. David Bradford submitted by Dey purports to offer expert opinions justifying virtually every one of Dey's defenses. Much of the testimony must be excluded, however, since Dr. Bradford's report contains inadmissible legal opinions, opinions that contravene this Court's legal rulings, rampant speculation, and unreasonable assumptions that are inconsistent with any proper damages determination under the False Claims Act. Accordingly, the testimony identified below should be excluded.[1]

OVERVIEW OF DR. BRADFORD'S REPORT

Parts B.3 through B.5 (¶¶ 22-26, 31-35). In Parts B.3 through B.5 of his report, Dr. Bradford begins his effort to legitimize Dey's false price reporting by describing federal statutes that encourage utilization of generic drugs (*id*. ¶¶ 22-26), and arguing that the dollar margins on generics must equal brands in order for pharmacies to have an incentive to dispense generics. He then opines that the high margins for generics are beneficial to the Medicare and Medicaid programs because they encourage generic utilization and lower overall costs. *Id*. ¶¶ 31-35.[2]

Part C. In Part C, Bradford opines that Dey's WAC prices are "list" prices that have a meaningful relationship to actual transaction prices, and that Dey's use of WAC prices is consistent with various publicly available descriptions. He also asserts that "Dey's AWP is treated as a requirement for market entry." Report at p. 38.

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[1] Dr. Bradford's expert report and appendices are submitted as Exhibits 1 and 1A, respectively. Due to space constraints, the United States does not address all of the errors in the report. Plaintiffs reserve the right to object to and seek exclusion of other testimony of Dr. Bradford not addressed in this memorandum.

[2] Bradford apparently does not believe that state laws mandating generic substitution in the Medicaid context provide sufficient incentive for providers to dispense generic drugs. *See, e.g.*, Mass. Gen. L. c. 112, § 12D.

Part D. This section of Bradford's report consists of 60 pages of summaries, characterizations of evidence, and purported opinions, accompanied by 130 pages of supporting appendices, all relating to the Medicaid program and purporting to show that federal and state governments knew and approved of Dey's false reporting conduct and intended to pay inflated reimbursements. Bradford asserts that federal Medicaid law establishes an "equal access" requirement which means that Medicaid agencies must pay the "marginal pharmacy" enough reimbursement to cover its costs.[3] He then concludes that the government's expert Mark Duggan, Ph.D., in developing his "but for" damages calculations, should have used sales transaction data obtained from wholesalers, and should have based damages calculations on the 95th percentile of prices paid by retail pharmacies. Report at pp. 44-52, and pp. 130-131 and Fig. 39. Bradford uses the same arguments and wholesaler transaction data to opine that "marginal" pharmacies would experience "accounting losses" if states reimbursed at the alternative prices used by Dr. Duggan. Report at p. 130 (¶ 287) and Fig. 39.

In Part D, Bradford also selectively summarizes and characterizes the so-called "government knowledge" evidence in the case and opines, in essence, that state and federal officials knew about inflated published prices but had a reason to pay inflated ingredient cost reimbursements. He maintains that dispensing costs are generally higher than dispensing fees, *id*. at 47-55, and that "cross-subsidization" between payment components is "common." *Id*. at 52. Despite the fact that *no* state or federal Medicaid official has testified to a policy of over-paying on the Estimated Acquisition Cost component to make up for a shortfall in dispensing fees,

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[3] Bradford asserts that marginal pharmacies "are the implicit targets of Medicaid payment policies." Report at p. 60 (¶ 135).

Bradford claims the information he summarizes suggests that states generally intended to cross-subsidize inadequate dispensing fees, *id*. at 52-57, and opines that "any shortfall in one component [i.e., the dispensing fee] must necessarily be made up by margins on other components." *Id*.[4] Bradford calculates a "dispensing fee shortfall" based on 2006 dispensing fee costs presented in an unpublished 2007 study by Grant Thornton. He then concludes that "more than half of the Plaintiffs' 'difference' calculation is attributable to the implicit dispensing payment component of ingredient component margins." *Id*. at 60.[5] Using Arkansas and Kentucky as examples, he argues that states generally intend to pay inflated acquisition costs, *id.* at 60 - 75, that states vary in their reimbursement policies and share information amongst themselves, *id*. at 75-81, and that state agencies could have chosen to use the Massachusetts WAC-based reimbursement methodology. *Id*. at 82.

Part E. Here, Bradford addresses Medicare reimbursement and contends that the United States has suffered zero damages. He glorifies the "role of home health care providers" in providing inhalation drug therapy, and asserts that these providers incur significant costs in compounding drugs and providing drugs and services to Medicare patients. *Id*. at pp. 109-112. He argues that before the Medicare Modernization Act of 2003 ("MMA"), underpayments on

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[4] In the lengthy Appendix E of his report, Bradford summarizes and characterizes Dey's evidence purporting to show "government knowledge," including numerous reports and testimony of various witnesses. In his report, Bradford opines that "States deliberately chose payment levels. . . . It is simply unreasonable to conclude that the levels of payment chosen by the states would have been different if pricing compendia had listed different published prices." Report at p. 76 (¶ 168).

[5] Bradford's specific calculations appear in various scenarios presented in Appendix G, under the columns entitled "Dispensing fee shortfall."

dispensing costs were cross-subsidized by inflated ingredient payments.[6] Bradford reviews regulatory and legislative events and concludes that the evidence "exonerates manufacturers" because the federal government was aware of inflated payments and could have chosen other reimbursement options, such as WAC. *Id*. at pp. 112-116. He then purports to quantify the Medicare cross-subsidy by showing how, after the MMA reduced ingredient cost payments beginning in 2004, CMS decided to pay significantly higher dispensing fees for inhalation therapy drugs, resulting in overall payments that Bradford says were higher than before the MMA. *Id*. at 117-120. Bradford concludes that Congress "could have made use of the WAC that Dey made available . . . and chose not to use it." *Id*. at p. 121. He then adjusts Dr. Duggan's damages calculations to show the difference between what Medicare would have paid had the DMERCs used Dey's WAC prices in their arrays, and what Medicare would have paid had Dey reported the 95th percentile of wholesaler prices to independent pharmacies (using Cardinal sales transaction data). *Id*. at 141-142 and Appendix H. The difference is zero. Bradford also calculates three alternative "Medicare dispensing fee shortfalls," described as the difference between the pre-MMA Medicare dispensing fee for inhalation therapy drugs ($5.00), and either (a) the dispensing fee established by CMS for 2005, (b) the dispensing fee established for 2006, or (c) the actual cost of dispensing inhalation therapy drugs estimated in a 2004 study prepared for purposes of lobbying CMS. *Id*. Appendix H.3.

[6] The United States seeks Medicare damages only for claims paid before the effective date of the MMA, January 1, 2004.

ARGUMENT

I. BRADFORD'S OPINIONS CONCERNING MEDICARE ARE LEGALLY IMPERMISSIBLE AND GROSSLY MISLEADING

A. Bradford's Opinion That Lawmakers Could Have Used WAC

Although Bradford presents his opinions concerning Medicare in Part E, at the end of his report, it is useful to examine them first because the weaknesses are illustrative of those in his other opinions and readily disposed of. Bradford "opines," in essence, that it was the federal government's fault that Medicare used AWP to determine reimbursement, that Medicare could have used Dey's WACs, and that Dey is not responsible for losses attributable to its false reporting of AWPs.

This testimony cannot stand. It requires no citation to authority to conclude that an expert's opinion that lawmakers were unwise to adopt a particular manner of regulation is inadmissible. Dey was obliged to conform its conduct to the law in existence at the relevant time, and it is misleading for an expert to suggest otherwise. Bradford's review of the regulatory and legislative history of Medicare's use of AWP, and his opinion that Congress and HHS could have used WAC as the basis for reimbursement, is nothing more than an effort to persuade the jury to second-guess the law as this Court and the Court of Appeals have interpreted it.[7]

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[7] Bradford's provision of inadmissible legal opinions is illustrated in paragraph 248 of his report, where he opines that "Congress' and HCFA's behavior reveals that they did not intend to set ingredient payments near average AC [acquisition cost]." Similarly, he provides legal opinion in paragraph 312, where he asserts, with no basis, that Medicare intended to "cover the costs of marginal providers," and that consequently the 95th percentile of pharmacy prices calculated from the wholesaler data is properly used in damages calculations. Bradford's testimony about what Medicare intended should be excluded.

Notably, Bradford's report says nothing whatsoever to suggest that Dey personnel were aware of the regulatory and statutory history Bradford cites to and relied on it in setting prices. The proffered evidence therefore has no relevance to the "knowledge" element of the FCA, or indeed to liability at all. Bradford characterizes his opinions as "economic," to seem as if they are confined to damages, but in fact he goes much further: he interprets, critiques and, in effect, amends the regulatory and legislative requirements to absolve Dey of liability for its false AWPs and then re-calculates damages on that basis.

B. Bradford's Pre-MMA and Post-MMA Comparisons

It is not necessary for purposes of this motion to wade into the weeds of Bradford's Medicare testimony, but Bradford's grossly misleading opinions relating to the MMA and the related dispensing fees cannot go unremarked. For example, in describing the supposed Medicare cross-subsidy, at 117-118 and Fig. 33, Bradford purports to illustrate Medicare payments for cromolyn sodium – a drug for which plaintiffs do not seek Medicare damages and which is therefore irrelevant. Bradford compares Medicare reimbursement for this drug, in 2004 versus 2005, to imply that before the MMA, Medicare intended to pay at least as much as it paid after its enactment. *See id.* at ¶ 257. Yet, as a matter of law, neither 2004 nor 2005 is relevant to that point.

The year 2004 is not representative of pre-MMA reimbursement because the MMA became effective January 1, 2004, and the statute established a one-year-only interim reimbursement rate for the relevant inhalation therapy drugs at 80 percent of AWP, as an interim transition to the ASP-based reimbursement that took effect January 1, 2006. Pub. L. 108-173 (§ 305(a)), 117 Stat 2066, 2238-2239, codified at 42 U.S.C. § 1395u(o)(1)(G) (referencing 68 Fed.

Reg. 50445). Before the MMA, Medicare paid at 95 percent of AWP.[8] A depiction of pre-MMA payments, before 2004, would show much higher payment levels resulting from inflated AWPs. Similarly, Bradford's depiction of post-MMA payments in 2005 with a high dispensing fee, is misleading because that year too was a transition year. The dispensing fee of $57 that Bradford uses was established by CMS as an interim fee for 2005 only, based on a report submitted by pharmacy lobbyists. 69 Fed. Reg. 47488, 47546-47550 (Aug. 5, 2004) (proposed rule) (Ex. 2 hereto); 69 Fed. Reg. 66236, 66425 (Nov. 15, 2004) (final rule) (Ex. 3). Subsequently CMS concluded that this fee was too high and reduced by establishing a $57 fee for only the first 30-day supply, a $33 fee for subsequent 60-day supplies, and a $66 fee for 90-day supplies, yielding an overall average fee of about $35.[9] Bradford's selection of these two idiosyncratic and therefore irrelevant years fails to support his purported opinion about a supposed cross-subsidy.

Bradford repeats the fallacy in his depiction of Medicare payments for compounded solutions of albuterol and ipratropium bromide, at 118-119 and Fig. 34. Here, however, his data are even more misleading. Bradford compares the typical 2005 payment for a 30-day claim for pharmacy-compounded solutions of albuterol and ipratropium bromide, with payment for a 30-day claim based on a new HCPCS code, J7616, introduced by CMS effective January 1, 2005.

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[8] Balanced Budget Act of 1997 (BBA), Pub. L. 105-33, 111 Stat. 462-463 (1997) (effective January 1, 1998). Before 1998, Medicare paid at 100 percent of AWP. 56 Fed. Reg. 59502, 59621 (Nov. 25, 1991).

[9] *See* Declaration of Mark G. Duggan, Ph.D in Support of Motion to Exclude Certain Testimony of W. David Bradford, Ph.D ("Duggan Decl.") (Ex. 4 hereto), Attachment A (Rebuttal Report) at p. 14 ("To estimate the analogous dispensing fee per 30-day period in 2006, I assume that the average user had twelve 30-day prescriptions during the year, which would yield an average dispensing fee of $35.").

The clear purpose of Bradford's comparison is to have the jury believe that in 2005, the government increased reimbursement for the pharmacy-compounded formulations Bradford discusses in paragraphs 235-238. In fact, the HCPCS code J7616 (which was eliminated effective January 1, 2006[10]) did *not* apply to the pharmacy-compounded albuterol and ipratropium bromide drugs at issue in this case. DMERC Medicare Advisories stated:

> Code J7616 . . . may only be used when these drugs are provided in combination by a manufacturer or repackager in a vial with a single NDC number. DuoNeb is one example of J7616. Despite the narrative description of the code, J7616 and J7617 must not be used for inhalation solutions of these drugs that are compounded by pharmacies."

See Duggan Decl. (Ex. 4), Attachment E (Region C DMERC DMEPOS Supplier Manual) at p. 21.4; *id*, Attachment D (LDC For Nebulizers, DMERC Region A, 2005) at 18-19. While DuoNeb is a Dey product, it is pre-compounded by Dey in the manufacturing process, not by the pharmacy, and it is *not* one of the drugs alleged in the government's complaint. Dr. Bradford's comparison is therefore unhelpful to a determination of any issue in this case.

C. Bradford's Medicare "Dispensing Fee Shortfalls"

Likewise, Bradford's calculations of Medicare "dispensing fee shortfalls" (at Appendix G to his report), which are based on dispensing fees established in 2005, are premised on the false legal assumption that Dey's pre-MMA liability for damages should be measured by reference to post-MMA law. Bradford is not qualified to make such a legal conclusion, and he no offers no support for it in any event. Again, Dey's conduct must be judged on the basis of the law in effect

[10] *See* Duggan Decl. (Ex. 4), Attachment C (Region C DMERC Medicare Advisory, Spring 2006) at 28-29.

at the time of the conduct, not on subsequently enacted law. The proffered Medicare evidence should thus be excluded.

In addition, Bradford's Medicare "dispensing fee shortfall" calculation mixes apples with pomegranates and is unreliable. The implication of Bradford's analysis is that the shortfall should be subtracted from Dr. Duggan's "difference" calculation. Putting aside the flawed premise of this exercise,[11] it fails because the post-MMA Medicare dispensing fees were promulgated based on estimates of ingredient cost reimbursements resulting from accurate price reporting by *all* pertinent drug manufacturers. *See* 70 Fed. Reg. 47488, 47549 (August 5, 2004).[12] Dr. Duggan's Medicare analysis calculates damages resulting solely from Dey's false price reporting (in the "Dey-only" scenario) or from the combined impact of Dey's and Roxane's false price reporting, and ignores the impacts of any inflated prices reported by other manufacturers. If one were to apply a "dispensing fee shortfall" as Bradford suggests, to be consistent with the assumption underlying the new CMS dispensing fee, it would need to be applied to a calculation total that assumes that *all* relevant drug manufacturers reported accurate prices, with an appropriate market share attributed to Dey. *See* Duggan Decl. (Ex. 4), Attachment A (Rebuttal Report) at p. 13. As explained by Dr. Duggan, such a calculation would result in Dey damages much higher than Dr. Duggan's original calculations. *Id*. at pp. 14-16. Bradford's calculations thus rest on a misleading and unreliable foundation and should be

[11] As argued above, this sort of "shortfall" analysis is inadmissible because it assumes, without basis, the legal conclusion that before 2004, Congress and CMS intended to pay (or cross-subsidize for) dispensing fees at post-2004 rates.

[12] It is evident from the discussion in the preamble to the rule that CMS would not have promulgated the same dispensing fee regime on the assumption that only Dey (or Dey and Roxane) and not other manufacturers reported accurate prices.

excluded. *See Bogosian v. Mercedes-Benz of N.A., Inc.*, 104 F.3d 472, 477, 479 (1st Cir. 1997); *Ed Peters Jewelry Co., Inc. v. C & J Jewelry Co*., Inc., 124 F.3d 252, 260 (1st Cir. 1997).

D. Bradford's Opinion That "Only a Fraction of the Claims Plaintiffs Assert Can Be Connected to Dey Sales"

Bradford opines that only a small portion of the Medicare claims for which the United States seeks damages can potentially be attributed to Dey's sales. He purports to identify Medicare claims that actually sought reimbursement for the subject Dey drugs, using information which Bradford says allows him to match the DMERC providers to the customers identified in Dey's sales transaction data. Report at 120 (¶ 258) and Appendix H.2.[13] This testimony is irrelevant. For purposes of liability, the FCA provides that liability shall attach to "any person who-- (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." For purposes of determining damages, the FCA allows recovery of "3 times the amount of damages which the Government sustains because of the act of that person." 31 U.S.C. § 3729. The government seeks damages caused by Dey's false price reporting, which caused overpayments for all drugs covered by the relevant HCPCS code, "regardless of which manufacturer's version is ultimately dispensed by the pharmacist." *City of New York v. Abbott Laboratories*, Civil Action No. 03-10643, MDL 1456, Memorandum and Order dated January 27, 2010 (Dkt #6863), at 13. Bradford's opinion is intended to confuse and mislead the jury regarding the applicable law, and it is irrelevant to any issue properly before the jury. Accordingly, it should be excluded.

[13] Bradford's report refers to Appendix H.1, but it is apparent he means to refer to Appendix H.2.

II. CERTAIN OF BRADFORD'S MEDICAID OPINIONS SHOULD BE EXCLUDED

A. Testimony By Bradford Concerning Encouragement of Generic Substitution

Bradford's testimony about the Hatch-Waxman Act (*id*. ¶¶ 22-26) is a clever effort to persuade the jury to think that Medicaid law and policy should be viewed in relation to the objectives of the Hatch-Waxman Act. This is not only incorrect, but improper legal opinion disguised as "economic" opinion. Any such inference is unfounded, and, in any event, is solely the province of the Court, not Dr. Bradford. *United States v. Newman*, 49 F.3d 1, 7 (1st Cir. 1995) ("It is not for witnesses to instruct the jury as to applicable principles of law, but for the judge.") (quoting *Marx & Co. v. Diners' Club, Inc*., 550 F.2d 505, 512 (2d Cir. 1977)).

Bradford's opinion that dollar margins on generics must equal those of brands in order to meet the generic substitution objectives of Medicaid and Medicare policy (*id*. ¶¶ 31-35) is improper for similar reasons. First, it is based on the unfounded assumption that Medicaid and Medicare, not to mention beneficiaries paying co-payments, should not benefit from price competition in the generic marketplace. Second, there is no law or policy that says dollar margins on inexpensive generics must be high enough to induce generic substitution. To the contrary, the Federal Upper Limit program, 42 C.F.R. § 447.332 (2006), is designed to strictly limit payments for multiple-source drugs, including multiple-source brand drugs, unless the physician certifies that the brand version is necessary. This creates an economic inducement for providers to dispense generics without any reliance on the inducement created by Dey's false price reporting. Similarly, most state Medicaid programs mandate generic substitution. *See* HHS OIG "Generic Drug Utilization in State Medicaid Programs," July 2006, OEI-05-05-00360 (Ex. 5 hereto), p. 2 ("Forty-one State Medicaid programs have 'mandatory

generic substitution' policies, which require that generic drugs be dispensed whenever a generic version of the drug is available."). These laws belie Bradford's assertion that government laws and policies justify reporting of false prices for the purpose of encouraging generic utilization. Additionally, Bradford's opinion, if accepted, would mean that the regulatory term EAC (as well as the regulatory terms "AWP" and "WAC") has no meaning (other than what manufacturers want it to mean), because, under Bradford's "dollar margin" logic, the term would have to incorporate a different payment rate depending on the cost of the drug. This is fundamentally at odds with Medicaid reimbursement methodology, where (outside the context of FUL and MAC-based reimbursement) Medicaid agencies generally apply their EAC formulas to brands and generics alike without regard to the cost of the drug. Alternatively, if Bradford means to suggest that Medicaid agencies must set their EAC rate at a level that ensures an adequate "dollar margin" for the cheapest generic, this necessarily means that states would pay, and pharmacists would reap, enormous "dollar margin" profits on all of the other more expensive drugs. Bradford's opinion is legally wrong, misleading, and should be excluded. *See United States v. Schneider*, 111 F.3d 197, 201-202 (1st Cir. 1997); *Pinkham v. Burgess*, 933 F.2d 1066, 1070-1071 (1st Cir. 1991). "Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *Daubert v. Merrell Dow Pharm., Inc*., 509 U.S. 579, 591 (1993) (internal quotation marks and citation omitted).

B. Bradford's Opinions Concerning State Medicaid Programs and Cross-Subsidization Are Inadmissible

1. Bradford's opinions regarding reimbursements to "marginal pharmacies" and "accounting losses" are unreliable.

Bradford's opinions concerning the "marginal pharmacy" and the need to base damages calculations on wholesaler transaction data, Report at 45-46, 48-49, 126-131, are legally flawed, unsupported by competent evidence, and calculated to mislead and confuse the jury into thinking it should decide for itself how much Medicaid programs should pay pharmacy providers, and base liability and damages determinations on that issue. A proper damages analysis in this case must determine what Medicare and Medicaid would have paid had Dey reported truthful prices. Bradford's "marginal pharmacy" opinions are unhelpful to this task.

First, the "marginal pharmacy" theory is contradicted by federal law. The governing regulation defines "estimated acquisition cost" as "the agency's best estimate of the price *generally* and currently paid by providers . . . ." 42 C.F.R. § 447.301 (2006).[14] Prices that are at or above the 95th percentile are not prices "generally" paid. Virtually all states use published prices to determine "estimated acquisition cost,"[15] and the testimony of state Medicaid witnesses was uniform in the understanding that "estimated acquisition cost" as used in state Medicaid programs is synonymous with the federal term.[16] To the extent Bradford's "marginal pharmacy" opinion is an opinion about the law, it is inadmissible. As previously noted, it is the province of

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[14] Bradford mis-quotes this definition as "the price 'generally and currently paid by providers . . . as determined by the program agency.'" Report at ¶ 102. The last clause in Bradford's quote is not and never has been a part of the definition.

[15] *See* Corrected Exhibit 24 to Declaration of George B. Henderson In Support of Motion For Partial Summary Judgment (Declaration of Myers and Stauffer LLC) (Master Dkt #6498, Sub. #447) at ¶ 24.

[16] *E.g.*, Ex. 6, 8/19/2008 Campana Dep. (Alaska) 164:16 - 166:17; Ex. 7, 8/21/2008 Campana Dep. (Alaska) 266:20 - 268:13; Ex. 8, 12/10/2008 Bridges Dep. (Arkansas) 30:21 - 31:13; Ex. 9, 12/3/2008 Gorospe Dep. (California) 201:4 - 202: 9; Ex. 10, 12/15/2008 Chapman Dep. (Colorado) 307:6 - 310:16; Ex. 11, 12/15/2008 Dubberly Dep. (Georgia) 39:20 - 43:8; Ex. 12, 12/3/2008 Cheloha Dep. (Nebraska) 350:13 - 352:10.

the judge, not a witness, to instruct the jury as to applicable principles of law. Obviously, Bradford has no legal training or experience and is not qualified to testify on matters of law.

Second, Bradford's attempt to impute a Medicaid intention to pay ingredient costs at the 95th percentile, whether characterized as legal or economic opinion, is pure speculation. There is no empiric evidence to test Bradford's theory because false price reporting in the manufacturing industry has precluded consistent and accurate determinations of ingredient costs. Information cited by Bradford is inconsistent with his 95th percentile theory. A 1994 paper that Bradford relies on shows that in 1991, states paid pharmacies, on average, 96 percent of *average* pharmacy costs, not 100 percent of the 95th percentile.[17] The authors concluded (at p. 41) that "Medicaid can pay less than average costs and still induce participation among pharmacies as long as payments are in excess of marginal costs." Bradford cites to a single example where he infers a specific level of desired pharmacy participation, involving an Arkansas state plan amendment in 1990 (*see* Report ¶ 146); yet even here he acknowledges that the "marginal pharmacy" for Arkansas at that time was the 70th percentile. His leap from this to the inference that all states, throughout the relevant time period, had a policy of ensuring participation at the 95th percentile, has no basis. No state official and no Medicaid policy document states that Medicaid must

[17] Adams, Kreling, Gondek, *State Medicaid Pharmacy Payments and Their Relation to Estimated Costs*, Health Care Financing Review 15, No.3 (1994) (Ex. 13 hereto). This paper was based on a study done under a contract with the Health Care Finance Administration, in response to a directive of Congress. According to the study, 1991 state Medicaid payments for ingredient costs were estimated to be 102% of actual ingredient costs, while dispensing fees were estimated to be 79% of actual dispensing costs. The authors opine (at p. 41), "It does not seem that it is the role of the public payer to ensure that the average costs of all pharmacies are covered."

overpay the ingredient cost of 95 percent of providers in order to ensure "access" to the "marginal" pharmacy.[18]

Bradford's supporting evidence consists mainly of evidence that pharmacy lobbying has sought to thwart efforts in some states to reign in escalating ingredient cost payments. This simply reflects a *consequence* of the false price reporting, namely that pharmacies became accustomed to inflated reimbursements and opposed reform. *Cf. New England Carpenters Health Benefits Fund v. First Databank, Inc.*, 602 F. Supp. 2d 277 (D. Mass. 2009). It says nothing about what Medicaid agencies would have paid had the false price reporting never occurred in the first place. As stated by the First Circuit, such evidence merely reflects "slow adaptation to shadowy industry practices, not ratification of it." *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 156, 171 (1st Cir. 2009). In any event, evidence of pharmacy lobbying does not provide a valid basis to quantify a supposed objective of all Medicaid programs respecting pharmacy participation.

With regard to Bradford's assertion that wholesaler data from Cardinal Health is the proper basis for determining "marginal pharmacy" costs, he neglects to mention that this data (and the other wholesaler data he references) was obtained in litigation pursuant to subpoena, was designated as "confidential" by the wholesalers, and has never been available to Dey or any Medicaid or Medicare program for price reporting or reimbursement purposes. *See* Ex. 14 (Ron

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[18] Certainly Medicare payment policy, both before and after the MMA, has adhered to the use of an *average* price, not a 95th percentile. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F.Supp.2d 277, 287-288 (D. Mass. 2006) (interpreting "average wholesale price" as used by Medicare); 42 U.S.C. § 1395w–3a (defining average sales price payment methodology).

Reich Dep. pp. 61, 197). Transaction data that has never been available to Dey for price reporting purposes and has never been available to the Medicare or Medicaid programs does not shed any light on what prices Dey could have reported or on what the Medicare or Medicaid programs would have paid had Dey reported truthfully. There is not a whisper of evidence to suggest that Dey's objective in setting its reported prices was to ensure "access" by the "marginal pharmacy." Consequently, the wholesaler data, and Bradford's resulting opinions, have no relevance to any issue in this litigation.

Furthermore, the Cardinal wholesaler transaction data is incomplete and unreliable. Cardinal witnesses testified that this data, consisting of data from Cardinal's "Disktrack" database, does not include rebates and other discounts not reflected in the invoice, and that it therefore overstates provider acquisition costs. Ex. 14 (Reich Dep. 60:14 - 61:17); Ex. 15 (Neil Warren Dep, 9/9/2008, 277:21-278:21). In this litigation, the impacts of rebates and other discounts is critical. The error in Bradford's use of this data is compounded because, in calculating the "accounting losses" that "marginal pharmacies" would purportedly suffer if Dr. Duggan's alternative prices were used, Bradford measures cost to the marginal pharmacy "by taking the 95th percentile price to customers in the 'INDEPENDENT' class of trade in the Cardinal data. Report at p. 130 n.293. Of course, the independent class of trade likely pays more than any other class of trade. In short, Bradford uses unreliable data to calculate the 95th percentile of the most extreme sub-set in the data. This misleading testimony should be excluded.

Bradford's methodology for calculating "accounting losses" to the "marginal pharmacy" is internally inconsistent with a major premise of other parts of his report. He calculates

"accounting losses" for only the Subject Drugs (Report at pp. 130-131), without regard to pharmacy income from other drugs. As he alludes to elsewhere, the subject Dey drugs are inexpensive, especially compared to brand drugs, and therefore they generate smaller dollar margins as compared to brand drugs (*id*. at 14-15). Bradford conveniently neglects to calculate whether "accounting losses" would occur for all drugs, including brands, assuming Dr. Duggan's methodology were applied across the board. Bradford's myopia on this point is internally inconsistent with his view that it is necessary to evaluate what would happen if Medicaid used Dr. Duggan's ASP+25% approach for *all* drugs. *See* Report at pp. 49-52.[19] Brand drugs account for a large majority of Medicaid expenditures. Duggan Decl. (Ex. 4), Attachment A (Rebuttal Report) at p. 6. Given that a 25% markup on expensive brand drugs would yield substantial dollar margins, it is highly likely that the marginal pharmacy would continue to profit under an ASP+25% payment regime. Bradford's internally inconsistent opinion should be excluded. *Ed Peters Jewelry Co., Inc.*, 124 F.3d at 260 (upholding exclusion of expert testimony on the ground that it was internally inconsistent).

2. Bradford's cross-subsidization and "dispensing fee shortfall" theory.

Bradford imagines a "but for" world in which, if Dey and all other drug manufacturers had reported truthful prices, state Medicaid agencies would have increased dispensing fees to

[19] By focusing on "accounting losses" for only the inexpensive Dey generic drugs, Bradford repeats the same error he makes in opining that the "dollar margin" on a generic drug must equal that of the brand drug. He ignores that, outside the FUL and MAC context, Medicaid programs generally use the same EAC formula for brands and generics alike, regardless of the cost of the drug. In Bradford's world, Medicaid agencies must set their EAC rates at levels needed to ensure a profitable "dollar margin" on cheap generic drugs, resulting in huge dollar margins on more expensive brands. This is logically and legally infirm.

levels consistent with the Grant Thornton study and/or would have disregarded the definition of "estimated acquisition cost." Report at 53-60, 130-131, 134, Appendix G. Bradford's "opinions" are flawed on multiple fronts.

First, the Court should foreclose Dey's attempt to have Bradford, an economist, give opinions about the intentions and knowledge of state and federal Medicaid officials, through characterizations of "government knowledge" evidence. *See, e.g.,* Report at 56-57, 60-76. The United States has previously pointed out that such "government knowledge" evidence is irrelevant in these cases. But even if such evidence is relevant, the inferences and conclusions to be drawn from that evidence, what agencies knew and intended, are disputed issues for the jury to decide, and inappropriate for expert testimony.

Second, Bradford's opinions concerning what might have happened had all drug manufacturers reported truthful prices are improper and speculative. This case is about Dey's conduct (and Roxane's conduct, if the cases are consolidated), and it is improper for Dey's expert to opine based on assumptions about changes in the behavior of other drug companies and speculative and imagined secondary effects on government dispensing fee payments. As demonstrated in the related case against Abbott Laboratories, when Abbott in 2001 changed its price reporting practices and reported prices that approximated actual acquisition costs, there was a direct and corresponding drop in Medicaid reimbursements; and there is no evidence that states increased dispensing fees, or that pharmacy providers stopped accepting Medicaid patients, or that Medicaid recipients were denied access to prescription drugs. Duggan Decl. (Ex. 4), Attachment A (Rebuttal Report) at pp. 4-5. A proper damages calculation in this case should consider only the direct effects of the defendant's falsity. Speculation about what would have

happened had all other pharmaceutical manufacturers reported truthfully will only confuse and mislead the jury. *See* Fed. R. Ev. 403.

Third, Bradford's assumptions are unsupported and speculative. Bradford's analysis effectively asks the jury to believe that, if manufacturers had reported prices in accordance with the alternative prices that Dr. Duggan uses (ASP+25%), then all state Medicaid agencies would have paid dispensing fees at the levels suggested by the Grant Thornton study. Of course, there is no evidence whatsoever to support such a conclusion. To begin with, the Grant Thornton study did not exist prior to 2007, and thus there is no basis for Bradford's implicit assumption that states were aware of the dispensing costs reported in that study and would have sought to reimburse at levels consistent with those costs. Moreover, elsewhere in his report, Bradford himself opines that Medicaid "payment policy is the result of a combination of economic, political and budgetary influences that result in a final rule which set [sic] Medicaid pharmacy payment at the levels states intended." *Report* at 60 (¶ 137). This belies the numerical "but for" quantification that Bradford espouses. In reality, Bradford's opinion is not about what states *would* have been paid if manufacturers had reported truthful prices; rather, it is an irrelevant policy opinion about what states *should* pay if prices were reported truthfully. The reality is that the history of false price reporting by Dey and other manufacturers has eliminated any reliable basis for determining what Medicaid agencies would have paid in dispensing fees in the absence of the fraud. This is a consequence of the fraudulent conduct, and Dey should not be allowed to rely on misconception and speculation to defeat liability and damages.

As Dr. Duggan has pointed out, the undisputed evidence demonstrates that when states have adjusted their payment methodologies to reduce the ingredient cost payments, they have

generally *not* made corresponding increases in their dispensing fees. Rebuttal Report at 5-7. And, as pointed out above, published literature indicates that, absent the levels of fraud at issue here, states would pay significantly less without compromising beneficiary access to drugs.[20] Bradford's unfounded speculation to the contrary is unreliable and should be excluded.

Finally, Bradford's calculation of Medicaid "dispensing fee shortfalls," see Report at p. 60 (¶ 135), pp. 134-136 & Figures 41 & 43, and Appendix G, rests on an extrapolation from a single unrepresentative state (Massachusetts) to 32 other states. See Duggan Decl. (Ex. 4) at Attachment B. Specifically, Bradford has calculated a "dispensing fee shortfall" for each state over the relevant time period by calculating a quarterly dispensing fee shortfall for Massachusetts only (using the Massachusetts dispensing fees), and then applying that shortfall to all other states in his Figures 41 and without regard to each other state's dispensing fee history. The Massachusetts dispensing fee is not representative of the dispensing fees of other states. *Id*. Dr. Bradford's extrapolation is therefore unreliable.

3. Bradford's Legal Analysis of a HCFA Appellate Board Ruling.

Bradford again improperly assumes the role of lawyer when he analyzes a 1991 HCFA Appellate Board ruling relating to Arkansas and concludes that "considering the ingredient component as separable from the dispensing component of a state's payment rule . . . would violate not only the spirit, but the actual language of the regulation." Bradford opines that "Dr. Duggan's differences methodology takes exactly the approach condemned by the HCFA Appellate Division in its ruling in the Arkansas dispute." Report at pp. 62-64 (¶¶ 144-148). The Appellate Board ruling (attached as Ex. 16) involved a dispute over a HCFA decision to withhold

[20] *See* Adams, et al., *supra*.

federal Medicaid funding because of Arkansas's use of an undiscounted AWP in determining EAC. Before 1989, Arkansas had reimbursed at 100% of AWP plus a dispensing fee of $4.01. After HCFA disapproved a state plan amendment and insisted that the state change its formula, Arkansas changed its reimbursement formula to AWP-10.5% and increased the dispensing fee to $4.16 plus .093 x EAC, effective August 1, 1989. HCFA withheld four months' worth of federal monies due to the State's delay in adjusting its formula. The Appellate Board ruled, in relevant part, that HCFA should reconsider whether the amount of the withholding should be based on the difference between what that state paid during the disallowance period and what it would have paid had the new payment system, including the higher dispensing fee, been in effect. *Id*. at pp. 11-12.

Bradford's characterization and opinion testimony should be excluded as impermissible legal opinion (see citations above) and because it is incorrect, misleading, and would confuse a jury. In the Arkansas case, the new dispensing fee was an amount known and approved by HCFA. Bradford's attempt to analogize the Appellate Board ruling to the instant case is wrong because there is no competent evidence regarding how much, if at all, each state would have changed its dispensing fee had Dey individually, or all manufacturers collectively, reported AWPs that were consistent with Dr. Duggan's methodology. In the Arkansas appeal there was complete certainty; in the instant case there is complete speculation.

C. Bradford's Opinions Concerning Payment Variation Across States, and His Use of Massachusetts As a Basis For Alternative Calculations

Bradford opines that "States could have copied the example of low-payment states such as Massachusetts," and that therefore "Massachusetts payment methodology based on a

published price can be seen as a threshold that was available to all." Report at p. 100, ¶ 212.[21] Bradford supports his position by characterizing state policies and intentions (using Kentucky and Arkansas as "illustrative" states) and he concludes that "Medicaid payments for Dey drugs are a result of state policy decisions that are dominated by political influences in each state and are not a result of the alleged conduct of Dey." *Id*. at 41; see *id*. at 103.

This opinion, and all the analysis that supports it, suffers from the same legal defect as Bradford's opinion that Dey is not responsible for Medicare overpayments because the Medicare program could have chosen to use the Massachusetts WAC-based methodology. Simply stated, Bradford applies the wrong law. Instead of recognizing existing federal and state Medicaid statutes and regulations, Bradford concludes, in effect, that lawmakers did not really intend to pay estimated acquisition cost and instead chose to pay Dey's falsely inflated AWPs in order to accomplish Bradford's imagined Medicaid policy objectives. This specious testimony must be excluded as unhelpful to the real issues in the case and misleading. No doubt there is evidence of "slow adaptation to shadowy industry practices," but any quantification of what governments would have done absent inflated price reporting consists of unfounded speculation, as argued above. If indeed Medicaid agencies would have made some adjustments to their methodologies, the historic false price reporting of Dey and others has eliminated any reliable basis for describing it. As the Supreme Court has consistently observed,"[t]he most elementary

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[21] Bradford thus claims that all state payments above the Massachusetts WAC-based levels cannot be causally attributed to Dey. *Id*. at 76 (¶ 169), 82 (¶ 180). In Appendix G of his report, Bradford calculates alternative Medicaid "differences" assuming that all states used the Massachusetts reimbursement methodology. Most of Dey's reported WACs were much less inflated than the AWPs, resulting in drastically reduced "differences" in Bradford's alternative calculations.

conceptions of justice and public policy require that the wrongdoer shall bear the risk of the uncertainty which his own wrong has created." *Bigelow v. RKO Radio Pictures, Inc.*, 327 U.S. 251, 265 (1946); *see also Story Parchment Co. v. Paterson Parchment Paper Co.*, 282 U.S. 555, 563 (1931) ("it is defendants . . . who must bear the risk of any uncertainty which their wrong has created.").

CONCLUSION

For the foregoing reasons, the Court should exclude Dr. Bradford's testimony as specified above.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above document to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

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